UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,503	08/28/1998	ROBERT D. AINSWORTH	11770US03	3597

23446 7590 02/26/2008

MCANDREWS HELD & MALLOY, LTD
500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/143,503	AINSWORTH ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 15 is objected to because of the following informalities: Claim 15 is not written in proper format. Note the example provided by the examiner in the last office action mailed May 3, 2007. Patentee's claim 15 omits the "." after the capital letters. Appropriate correction is required.

Recapture, Rejection under 35 U.S.C. 251

Claims 18-64 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that Patentee previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The examiner has carefully detailed the rationale behind the recapture rejection in the previous office action. Patentee presents comments rebutting that rejection, and they have been carefully considered. However, whether or not a claim is prevented under 35 U.S.C. 251 requires more than an analysis of what subject matter was present in the claims during prosecution, and how those claims were amended. MPEP 1412.02 sets forth a three step test for recapture. In addition to analyzing and comparing claim embodiments of the prosecuted claims, the reliance by Patentee to define the original patent claims over the art can be by way of presentation of new/amended claims to define over the art, or an argument or statement by Patentee that a limitation of a claim defines over the prior art. Accordingly, there can be a recapture even if claims were not amended during the prosecution of the original application which resulted in the patent.

Turning to the prosecution history of the '121 patent, Patentee's attention is directed to the amendment filed December 1, 1995, Paper #8, pages 3-5. Patentee argues the allowability of claims 5-10 over the prior art by setting forth arguments directed to the tensile modulus and tensile strength embodiments set forth in claim 5 in comparison to the prior art applied. Specifically, Patentee states that the claims are allowable over Hamlin because Hamlin, while showing a tensile modulus of more than 300,000, does not show a tensile strength above 10,000 psi. Patentee even provides a copy of the International Plastics Selector-Plastics Digest in support of the argument.

Patentee's claim 18 does not recite the tensile modulus of more than 300,000 psi. Claims 53 and 57 do not recite the tensile strength above 10,000 psi. Since these

embodiments were specifically argued in the '121 patent as the defining feature in view of the prior art, there is an improper recapture of surrendered subject matter.

An exception to the rule that an argument can qualify as recapture, is when the argument a general statement regarding the claims as a whole, and not referenced to a specific claim limitation. However, Patentee clearly references these two claim limitations, tensile modulus and tensile strength. Accordingly, the recapture rejection is proper.

Claim Rejections - 35 USC § 102

Claims 57-64 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beisel, WO 94/01160 with reference Muni et al., U.S. 5,316,706 and to Bennett et al., U.S. 5,221,728.

Beisel discloses an epidural catheter which may be inserted intravascularly and in addition the catheter's objective is to lower the incidence of blood vessel puncture, for example. See page 5, lines 8-15. Accordingly, Beisel discloses the claimed preamble "intraluminal catheter" since the epidural space in an intraluminal space as claimed, and Beisel also discloses the intended use of the device, for advancement into the patient's vasculature. Patentee's arguments as to the preamble are noted, however, it is well settled that the intended use of a device is not accorded much patentable weight, particularly when the body of the claim, as here, does not refer back to the preamble or otherwise breathe "life and vitality" into the preamble.

Regarding the body of the claim, Beisel discloses the shaft portions comprising PEEK and the claimed "tensile modulus greater than 400,000 psi." See page 7, third column, last line, the data for PEEK, 0.51 x 10^6 psi or 510,000 psi. Patentee also claims an elongation at break of greater than 50%, greater than 60% (claim 59) while Beisel is silent as to the elongation at break data, which is not uncommon in the catheter art.

However, as stated in the previous office action, the examiner takes the position that the Beisel catheter inherently possesses this characteristic as evidenced by Bennet. See, for example, Bennett, column 5, lines 45-60. A PEEK polymer was extruded and tested for modulus of elasticity, tensile strength and elongation at break. Note that the "modulus of elasticity" (also known as "flexural modulus", "tensile modulus," or more accurately, "tensile modulus of elasticity") cited by Bennett (2.4 GPa) is similar to that disclosed by Beisel, (3.5 GPa). The tensile strength of Bennett (107 MPa) is similar in range to that disclosed by Beisel (93.8 MPa). However, Beisel does not disclose an elongation at break. Bennett shows that a PEEK polymer with the same other characteristics of Beisel has an elongation at break of 156%. Accordingly, the examiner takes the position that Beisel inherently discloses the modest elongation at break claimed by Patentee, being greater than 50% (claim 57) and 60% (claim 37).

Muni is again relied on to exemplify that the concept of extruding PEEK (column 4, line 33) angioplastic catheters to improve stiffness and pushability was well known when the Beisel invention was conceived in the early 90's. Beisel discloses the catheter

may be extruded on page 10, lines 12, and Muni is relied on to show what this process involves.

Regarding the elongation at break, Patentee argues (page 5, lines 9+ of the response filed February 5, 2007) that tensile modulus, strength and elongation are properties which are inter-related and vary with the material processing conditions, particularly with regard to crystallinity and the manner in which the polymer is processed. While some of these issues are not disputed, the examiner still does not agree the claims are allowable for the following reasons.

Firstly, elongation at break is hardly ever discussed in the catheter art, accordingly, the absence of a disclosure of elongation at break in the prior art cannot generate the basis of a novel invention. Secondly, an elongation at break greater than 50%, or 60%, is a modest range. There is nothing unusual about this embodiment which one would not expect to find in the prior art. Thirdly, the Bennett '728 patent is provided to show an elongation at break of 156% for commercial PEEK (VICTREX PEEK 450 G manufactured by ICI). See column 5, lines 44-60. As stated in Patentee's '121 patent, the particularly preferred resin for the outer tubular member is formed of PEEK (grade 381) from VICTREX. This information, in addition to the information provided by Beisel, page 7, Table 1, shows how similar these polymers are in terms of mechanical properties. Fourthly, although Patentee argues that the manner of polymer processing is critical to the final properties of the polymer (and there is no disagreement here), the examiner points out that Patentee has not disclosed any extruding technique which would yield a catheter having unexpected properties, nor are these embodiments

claimed in a product by process type claim, even if the particular polymer processing had been disclosed. Accordingly, Patentee's arguments are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-22, 26, 27, 31-48, 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beisel, WO 94/01160 in view of Goltzer, US 4,973,305 with reference to Muni et al., U.S. 5,316,706 and Bennett et al., U.S. 5,221,728.

As stated in the previous office action, Beisel discloses an epidural catheter that is inserted intravascularly. Accordingly, Beisel discloses an intraluminal catheter for percutaneous insertion as claimed in the preamble. See Beisel, page 2, lines 13-23. Regarding the body of the claim, Beisel discloses that the stiff inner tube 12 may comprise PEEK (page 6, line 21). Distal portion 10 comprises the soft outer tube and anticipates the claimed more flexible distal shaft portion. Regarding the tensile strength, note page 7 and the tensile strengths listed therein. For PEEK, the tensile strength given is 13.6×10^3 psi, or 136,000 psi. Regarding the extruded limitation of the proximal shaft portion of claim 18, and noting the limitations of claims 51 and 52, see Beisel, page 10, line 12, which states that the epidural catheter can be constructed by known manufacturing processes "such as extrusion, drawing and the like." The examiner takes

the position that this disclosure anticipates the claim portion directed to the extruded proximal shaft.

In the alternative, Muni is cited to exemplify that the concept of extruding PEEK (column 4, line 33) angioplastic catheters to improve stiffness and pushability was well known when the Beisel invention was conceived in the early 90's. Accordingly, it would be obvious to one of ordinary skill in the art to extrude inner PEEK tube 12 of Beisel according to Muni so that the catheter exhibits improved pushability.

Patentee has now amended claim 18 to require a dilatation balloon on the distal shaft portion. The examiner takes the position that Beisel discloses all of Patentee's claim 18 embodiments with the exception of the balloon.

Goltzer '305 discloses an epidural catheter with a distal balloon retention means 12. See especially figure 2 on sheet 2. The purpose of the balloon is to anchor an epidural catheter securely in place for extended lengths of time. See column 2, lines 10-28. Beisel does not disclose a balloon anchoring device, however, it would be obvious to one of ordinary skill in the art to apply a Goltzer balloon to the Beisel shaft for the purpose of anchoring the Beisel shaft if the epidural catheter were desired for long term placement.

Regarding claim 19, Beisel discloses the PEEK on page 7.

Regarding claims 31-34, 53+, note again page 7 and the tensile/flexural modulus disclosed therein. The third column discloses a PEEK tensile modulus of 0.51×10^6 psi, or 510,000 psi. Regarding claim 35, note that the PAEK polymer has a tensile strength of 17.6×10^3 psi. Regarding claims 43-48 reciting the intended use, note that the Beisel

catheter is inserted intravascularly, and there is discussion of preventing "blood vessel puncture" on page 5, line 13.

Regarding claims 20, 21, 37-42, 55-56, reciting the elongation at break, again, the examiner admits that Beisel is silent as to the elongation at break data, which is not uncommon in the catheter art. However, the examiner takes the position that the Beisel catheter inherently possesses this characteristic as evidenced by Bennet. See, for example, Bennett, column 5, lines 45-60. A PEEK polymer was extruded and tested for modulus of elasticity, tensile strength and elongation at break. Note that the "modulus of elasticity" (also known as "flexural modulus", "tensile modulus," or more accurately, "tensile modulus of elasticity") cited by Bennett (2.4 GPa) is similar to that disclosed by Beisel, (3.5 GPa). The tensile strength of Bennett (107 MPa) is similar in range to that disclosed by Beisel (93.8 MPa). However, Beisel does not disclose an elongation at break. Bennett shows that a PEEK polymer with the same other characteristics of Beisel has an elongation at break of 156%. Accordingly, the examiner takes the position that Beisel inherently discloses the modest elongation at break claimed by Patentee, being greater than 50% (claims 20, 57) and 60% (claim 37).

Claims 18, 24, 25 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muni et al., U.S. 5,316,706 with reference to Beisel, WO 94/01160. Muni discloses the balloon angioplasty catheter (column 3, line 58) but fails to disclose the catheter properties. Beisel is cited to exemplify that the ranges cited by Patentee are known in the art for PEEK intravascular

catheters. Accordingly, the examiner takes the position that Muni inherently discloses the claimed range. In the alternative, it would be obvious to one of ordinary skill in the art to make the Muni catheter with the tensile strength, tensile modulus as shown by Beisel so that the catheter would be able to traverse blood vessels without puncturing the walls of the blood vessels. Regarding claim 25, the feature recited is inherent for the operability of a balloon catheter.

Claim Rejections - 35 USC § 103

Claims 28-30, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beisel, WO 94/01160 with reference to Muni et al., U.S. 5,316,706. Regarding claims 28-30, Patentee merely reverses the layering of the Beisel catheter, requiring that the proximal portion of the outer tubular member be made of the extruded material having the increased tensile strength. However, it is well established that the rearrangement of parts of *prima facie* obvious in the lack of a showing of criticality. See MPEP 2144.04 IV.C., entitled "Rearrangement of Parts," and note that the examiner may use legal precedent to provide the rationale supporting obviousness in this situation. In view that the examiner can find no evidence of unexpected results in the specification that would support patentability of this simple reversal, these claims must be rejected. Regarding claims 49 and 50, citing the length of the catheter, the Beisel length is recited on page 5, lines 29-35 as being a preferred length of 91.4 cm. Clearly, the Beisel catheter is not intended to be limited to this exact length. Further, it is well established that catheter lengths vary dependent on patient need, and are selected

according to the size of the patient. An infant would have a smaller sized catheter than a large adult.

Claims 23, 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al., '706 in view of Beisel, WO '160 as applied to claims 18, 24 and 25 above, and further in view of Cornelius et al., US 5,423,754. Muni discloses a balloon angioplasty catheter but fails to detail the features commonly applied to these catheters. The Muni patent is primarily dedicated to the type of polymers and the method of making the catheter shaft. Patentee's claims 23, 1-17 point out the particular catheter structure desired. Cornelius exemplifies that the structure of inner and outer catheters, and the dilation balloon, the guide wire lumen, and with the various hard and soft areas are well known features in a balloon angioplasty catheter. It would be obvious to one of ordinary skill in the art to provide the Muni angioplasty catheter with angioplasty catheter features as shown by Cornelius, in order to make the Muni catheter operable for its intended purpose. An angioplasty catheter will not be operable, or will be barely operable (an imagined embodiment without a guide wire lumen), without the Cornelius features.

Response to Arguments

Patentee's arguments filed February 5, 2007 have been fully considered but they are not persuasive. Most of Patentee's arguments have been responded to, however, Patentee also argues that dependent claims should be allowed because of the shaft

dimensions and the function of the catheter needed for angioplasty are different than those needed for epidural catheters because epidural catheters are not necessarily threaded through tortuous anatomy. This is not persuasive for the following reasons.

Most importantly, Beisel discusses the intravascular placement of the catheter on page 2. On page 5, the purpose of the Beisel catheter is stated as lowering the incidence of blood vessel puncture. Additionally, Patentee's independent claim 1 is not directed an angioplasty catheter or a catheter that it so be inserted into the vascular system. The claim is silent as to the feature, as well as the dependent claims 2-17. Claim 18 describes "an intraluminal balloon dilatation catheter for percutaneous insertion and transluminal advancement into a patient's vasculature." This limitation is shown by Beisel as described previously. Further, the intended use of a device, even if Patentee claimed the catheter was intended for angioplasty, does not have much patentable weight unless the body of the claim refers back to the preamble or otherwise breathes life and vitality into the preamble. Independent claims 53 and 57 are similar. Neither of the claims require that the intraluminal catheter be an angioplasty catheter. Accordingly, Patentee's arguments that the claims define over the prior art for these reasons are not persuasive. The examiner realizes that angioplasty catheters may follow a more tortuous path, however, this is does not mean that the Beisel catheter is not identical to the claimed subject matter. Epidural catheters have the added problem of being used in highly sensitive tissue, and must also have the pushability and navigation abilities that are required for angioplasty catheters. Hence the reason these catheters can comprise the same materials.

Conclusion

Patentee's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Patentee is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615